IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LIABILITY LITIGATION This Document Relates to: Second Amended Master Long Form Complaint For Personal Injuries And Damages, And Demand For Jury Trial (ECF No. 2505)	Master Docket: No. 21-mc-1230-JFC MDL No. 3014 (Oral Argument Requested)

MEMORANDUM OF LAW IN SUPPORT OF PHILIPS RS NORTH AMERICA LLC'S MOTION TO DISMISS PURSUANT TO FEDERAL RULES OF CIVIL PROCEDURE 12(b)(1) AND 12(b)(6)

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Defendant Philips RS North America LLC ("Respironics") respectfully moves to dismiss Plaintiffs' Second Amended Master Long Form Complaint for Personal Injuries and Damages (ECF No. 2505) (the "PISAC") pursuant to Federal Rules of Civil Procedure 12(b)(1) and (6). Respironics previously moved to dismiss Plaintiffs' master personal injury complaint, in its entirety, on multiple grounds. *See* ECF Nos. 1345-46. The Special Master recommended dismissing certain, but not all, of Plaintiffs' claims. *See* ECF No. 2271 ("R&R"). The Court adopted the R&R in part and granted Plaintiffs leave to amend in order to plead (i) facts to attempt to support their omission claim, (ii) their negligent recall and negligent failure to recall claims as separate counts, (iii) product liability act ("PLA") claims in place of subsumed counts, and (iv) each of their state consumer protection claims as separate counts. *See* ECF Nos. 2471-72.

Despite having another opportunity to amend their complaint, guided by specific instructions from this Court, Plaintiffs' claims remain deficient in myriad ways. Among other defects, (i) their now separately stated negligent execution of the recall and negligent failure to recall claims remain preempted, (ii) their negligent execution of the recall claim remains subject to the primary jurisdiction doctrine, (iii) they still assert common law claims that are subsumed by PLAs, (iv) their amended fraud claim still fails to plead the special relationship required to allege fraud by omission in certain states (an issue identified but not ruled on in the earlier briefing round), and (v) their separately pled consumer protection claims are foreclosed on numerous statute-specific grounds. This Court should dismiss these claims with prejudice.

ARGUMENT

I. PLAINTIFFS' NEGLIGENT RECALL/FAILURE TO RECALL CLAIMS FAIL.

A. The Negligent Execution of/Failure to Recall Claims Are Preempted.

A manufacturer's recall and post-recall conduct is subject to FDA regulation and oversight. 21 U.S.C. § 360h(e) (granting the FDA "recall authority"); *see also Gates v. Medtronic, Inc.*, 192

F. Supp. 3d 704, 710-11 (W.D. Tex. 2016) ("The law is clear that the FDA regulates in this area"). The FDA may request that a firm initiate a recall, 21 C.F.R. § 7.45, and once a recall is initiated, the FDA regulates communications and actions regarding the recall. 21 U.S.C. §§ 360h(a)(2), (b).

Congress has impliedly preempted claims that seek to enforce the Federal Food, Drug, and Cosmetic Act ("FDCA") and FDA regulations or that seek recovery based upon alleged non-compliance with the FDCA and FDA regulations. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001) (noting FDA has "a variety of enforcement options."). Plaintiffs' negligent failure to recall and negligent execution of the recall claims (**Counts VI(1) *and* VI(2)**), challenging when and how Respironics should have performed the recall, improperly attempt to step into the FDA's shoes in regulating recalls and are subject to implied preemption.

First, "Congress intended the Secretary of FDA to have discretion as to when to seek recall." *Nat'l Women's Health Network, Inc. v. A. H. Robins Co.*, 545 F. Supp. 1177, 1181 (D. Mass. 1982); 21 U.S.C. § 360h(e). Plaintiffs fail to identify or articulate any state law duty requiring the initiation of a recall without FDA involvement despite having leave to attempt to do so. Instead, Plaintiffs rely on FDA inspection observations, grounded in FDA regulations (PISAC ¶¶ 8, 11, 168, 171), to allege that Respironics should have initiated a recall sooner. Thus, Plaintiffs' negligent failure to recall claim reflects a quintessential effort to privately enforce the FDCA that is "foreclosed" by preemption. *Nat'l Women's Health Network*, 545 F. Supp. at 1181.

Second, Plaintiffs' negligent execution of the recall claim encroaches upon the FDA's exclusive province to oversee and assess the adequacy of a medical device recall. The PISAC cites the FDA's notification order under section 518(a) of the FDCA, PISAC ¶¶ 286-290, 292, 433, acknowledges that Respironics needed "authorization from the FDA to begin a repair and/or replacement process," *id* ¶ 434, and notes that Respironics is working with the FDA to implement

the recall, *id.* ¶¶ 274-75, 282-83. Thus, Plaintiffs recognize that the FDA has authority to oversee the repair, replacement, and refund of the devices, and is exercising that authority. While the R&R pointed to Plaintiffs' allegation that Respironics "assumed duties to exercise reasonable care in issuing and implementing the recall" as an indication that their negligent recall claim did not rely on section 518(a), that generous reading is inconsistent with PISAC allegations because (i) the PISAC's repeated FDCA-based allegations contravene Plaintiffs' attempted reliance on conclusory statements of purported state law duties, (ii) any purported "state law duty to use reasonable care in undertaking a recall" remains preempted because assessing whether Respironics "could have or should have performed a better recall . . . require[s] the court to scrutinize . . . [r]ecall notices and remedies," *Cohen v. Subaru of Am., Inc.*, No. 120CV08442JHRAMD, 2022 WL 721307, at *38 (D.N.J. Mar. 10, 2022), which the FDCA regulates, and (iii) "applying negligence law of more than twenty states to . . . recall efforts would undermine the [federal regulation]'s comprehensive statutory scheme for commencing and carrying out recalls." *Id.* at *40; *see also Gates*, 192 F. Supp. 3d at 712 (negligent recall claim preempted where plaintiffs sought to use "common-law tort duties" to impose requirements for carrying out the recall that "add to or differ from those . . . imposed by the FDA"). Given the FDCA's detailed requirements governing a medical device recall, Plaintiffs' negligent execution of the recall claim is preempted.

B. The Negligent Execution of the Recall Claim Fails Under the Primary Jurisdiction Doctrine.

Primary jurisdiction "comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body[.]" *CSX Transp. Co. v. Novolog Bucks Cnty.*, 502 F.3d 247, 253 (3d Cir. 2007), *as amended* (Sept. 14, 2007) (quoting *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 63-64 (1956)). "[W]hen an activity is arguably subject to an administrative agency's

expertise, such as the FDA, federal courts must defer to the exclusive competence of that agency." *In re Human Tissue Prods. Liab. Litig.*, 488 F. Supp. 2d 430, 432 (D.N.J. 2007) (citation omitted). This Court has observed that "courts are not to get involved with what the FDA does in regulating the matters that are subject to . . . its jurisdiction."[1] Viewed through the Court's primary jurisdiction framework, execution of the recall is a matter over which the FDA has exclusive enforcement authority, barring Plaintiffs' negligent execution of the recall claim.[2]

To evaluate primary jurisdiction, courts in the Third Circuit weigh whether (i) "the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise," (ii) "the question at issue is particularly within the agency's discretion," (iii) "there exists a substantial danger of inconsistent rulings," and (iv) "a prior application to the agency has been made." *Baykeeper v. NL Indus., Inc.*, 660 F.3d 686, 691 (3d Cir. 2011) (citation omitted) (Vanaskie, J.). Although the Special Master found that "abstention under the primary jurisdiction is not warranted," his analysis appears to have focused on a negligent ***failure*** to recall theory—particularly in his assessment of factors (i) and (ii). *See* R&R at 26-28. When focused on a negligent ***execution*** of the recall theory, each factor weighs in favor of deferral to the FDA's jurisdiction.

First, execution of Respironics' recall involves technical and policy considerations within the FDA's expertise. *See* 21 C.F.R. § 7.42(a) (outlining technical elements relevant to recall); PISAC Ex. 72 (Section 518(b) Notice) at 12 (acknowledging that remedial measures in this case "may present significant risks" and thus require the FDA's consideration); *see also Clark v. Actavis Grp. hf*, 567 F. Supp. 2d 711, 719 (D.N.J. 2008) ("[I]t is the FDA, not this Court who has the

[1] Tr. at 9, Mot. to Dismiss Hr'g, *SoClean* (Feb. 21, 2023) (ECF No. 104).
[2] The Court's position stands in contrast to the R&R's finding that determining the reasonableness of Respironics' recall "falls squarely with the conventional experience of judges." R&R at 26.

expertise in modifying the procedures associated with the recall.").

Second, oversight of the recall is particularly within the FDA's discretion. "[R]egulations implementing the [FDCA] vest the FDA with the authority to monitor and supervise product recall," and "set forth specific recall procedures whereby the FDA assumes control over monitoring recalls and assesses the adequacy of a firm's efforts in undertaking the recall." *Human Tissue*, 488 F. Supp. 2d at 432 (citing 21 C.F.R. §§ 7.40-7.59). The R&R relied on *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, 2020 WL 7418006, at *12 (D.N.J. Dec. 18, 2020), in analyzing this factor. However, no recall claims were at issue in *Valsartan*. Recall claims under FDA's active oversight present a different paradigm that directly implicates primary jurisdiction.

Third, judicial action poses a clear and substantial danger of inconsistent rulings given that the FDA's active oversight of the voluntary recall is both material and ongoing. *See* PISAC Ex. 72 (Section 518(b) Notice) at 2 (contemplating an order requiring Respironics "to submit a plan to repair, replace, and/or refund" the devices); *see also Harshbarger v. Pa. Mut. Life Ins. Co.*, No. 12-6172, 2014 WL 1409445, at *6 (E.D. Pa. Apr. 11, 2014) (finding courts should not intervene where, as here, "doing so would place [them] squarely in the realm reserved" for an agency).[3] Indeed, in contrast to the R&R's suggestion that the FDA has already made a determination on the reasonableness of the execution of the recall, the FDA itself states that its "evaluation of the information provided by Philips ***is ongoing***." PISAC ¶ 297 n.410 (emphasis added).

Finally, as the R&R noted and the PISAC confirms, the FDA continues to actively oversee and authorize elements of the recall and replacement program. R&R at 27; *see also* PISAC ¶¶ 191,

[3] The R&R distinguished *Harshbarger* on the ground that the Court here will not need to analyze FDA regulations, R&R at 27, but it is unclear how the Court would determine whether the recall was negligently executed without referring to the specific recall procedures outlined in the Federal Regulations that are cited in the PISAC as a basis for liability. *See, e.g.*, 21 C.F.R. §§ 7.40-7.59.

297 n.410. Even if Plaintiffs' negligent recall claim (**Count VI(2)**) were not preempted, dismissal under the primary jurisdiction doctrine is warranted. *Baykeeper*, 660 F.3d at 691.

C. Negligent Failure to Recall is Not a Cause of Action in Two States.

Plaintiffs' negligent failure to recall claim (**Count VI(1)**) should be dismissed insofar as it is alleged under Illinois and Oklahoma law because those states do not recognize it as an independent cause of action.[4] This Court's Opinion recognized that Respironics objected to the R&R on this basis, but did not rule on the objection. *See* ECF No. 2471 at 4, 6.

II. NEGLIGENCE *PER SE* IS NOT A CAUSE OF ACTION IN FOUR STATES.

The PISAC attempts to state a negligence *per se* claim (**Count XV**) under 23 states' laws. But in Delaware, Oregon, Rhode Island, and Wisconsin,[5] negligence *per se* is not an independent claim. Rather, it is a standard of care that a law imposes within a cause of action for negligence.[6]

III. STATE PRODUCT LIABILITY ACTS SUBSUME CERTAIN CLAIMS.

A. Plaintiffs' Indiana Breach of Warranty Claims Are Subsumed.

The Indiana Product Liability Act ("IPLA") governs all actions for "physical harm caused

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[4] *See Modelski v. Navistar Int'l Transp. Corp.*, 707 N.E.2d 239, 247 (Ill. App. Ct. 1999) (finding no extra-statutory duty to recall or retrofit products); *Wicker ex rel. Est. of Wicker v. Ford Motor Co.*, 393 F. Supp. 2d 1229, 1236 (W.D. Okla. 2005) ("Oklahoma does not recognize a post-sale duty to warn or retrofit a product.") (citations omitted).

[5] *See Gordon v. Nat'l R.R. Passenger Corp.*, No. CIV.A. 10753, 2002 WL 550472, at *7 (Del. Ch. Apr. 5, 2002) ("[N]egligence per se is not itself an independent claim."); *Hammick v. Jacobs*, No. 3:19-cv-00200-JR, 2020 WL 6135464, at *5 (D. Or. Oct. 19, 2020) ("[T]he doctrine of negligence per se does not create a cause of action . . . .") (citation omitted); *Kurczy v. St. Joseph Veterans Ass'n, Inc.*, 820 A.2d 929, 947 (R.I. 2003) ("[T]he violation of a statute or an ordinance is not negligence *per se* but is to be used by the trier of the facts merely as an aid in determining that issue on consideration of all the evidence.") (citation omitted); *D.L. by Friederichs v. Huebner*, 329 N.W.2d 890, 917 (Wis. 1983) ("Negligence *per se* ordinarily refers to a form of ordinary negligence that results from violation of a statute. The violation of the statute is the deviation from the standard of care and supplies one element of a negligence cause of action: breach of duty. Other issues such as causation and contributory negligence remain.") (citations omitted).

[6] The R&R recommended dismissal of Plaintiffs' negligence *per se* claim under the laws of 15 states on this basis, but did not consider Delaware, Oregon, Rhode Island, and Wisconsin law.

by a product; regardless of the substantive legal theory or theories upon which the action is brought." Ind. Code § 34-20-1-1. The IPLA subsumes all breach of warranty claims (**Counts X *through* XII**) where, as here, Plaintiffs allege only personal injury related to a defective product.[7]

B. Plaintiffs' Fraud Claim is Subsumed by Four States' Product Liability Acts.

Because Plaintiffs claim personal injury damages related to a product defect, their fraud claim (**Count XIII**) is subsumed by the Kansas, Mississippi, Ohio, and Tennessee PLAs. *See, e.g., In re Valsartan*, MDL No. 2875, 2021 WL 364663 at *14 (D.N.J. Feb. 3, 2021) (fraud claim in personal injury complaint was subsumed by Kansas and Tennessee PLAs).[8]

C. Certain Consumer Protection Claims Are Subsumed.

Plaintiffs' Indiana, Mississippi, and New Jersey consumer protection claims (**Counts XVI(14), (22), (27)**) are subsumed by those states' PLAs, which govern ***all*** actions for physical harm caused by an allegedly defective product. *See* Ind. Code § 34-20-1-1 (Indiana PLA governs "regardless of the substantive legal theory or theories upon which the action is brought"); Miss. Code Ann. § 11-1-63 (Mississippi PLA applies "in ***any*** action for damages caused by a product") (emphasis added); N.J.S.A. 2A:58C-1 (New Jersey PLA governs "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim . . . .").[9]

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[7] *See, e.g., Palm v. Taurus Int'l Mfg., Inc.*, No. 22-CV-337, 2022 WL 17714600, at *4-5 (N.D. Ind. Dec. 15, 2022) (holding that, because "[e]ach warranty claim alleges only [plaintiff's] personal injury and injury originating from a product defect[,]" the express and implied warranty claims "are subsumed by the IPLA") (citation omitted).

[8] *See also Young v. Bristol-Myers Squibb Co.*, No. 416CV00108, 2017 WL 706320, at *4 (N.D. Miss. Feb. 22, 2017) ("fraud claims are subsumed by the [Mississippi PLA] unless the claims are 'unrelated to the alleged defects'") (citation omitted); *McFarland v. Ethicon, Inc.*, No. 20-cv-02188, 2020 WL 4464401, at *2 (S.D. Ohio, Aug. 4, 2020) (fraud claim in medical device case was subsumed by Ohio PLA).

[9] *See also In re Valsartan*, 2021 WL 364663, at *9 (New Jersey CPA claim in personal injury master complaint was subsumed by New Jersey PLA because the two claims were "nearly

IV. PLAINTIFFS IMPROPERLY ASSERT THEORIES OF LIABILITY UNAVAILABLE UNDER FOUR STATES' PRODUCT LIABILITY STATUTES.

Only limited theories of liability are available under the Kansas, Louisiana, New Jersey, and Ohio PLAs.[10] Plaintiffs plead common law causes of action under their PLA claims without regard for these limits.[11] These claims (**Counts XXV, XXVI, XXVIII, XXIX**) must be dismissed (or struck) to the extent they are based on theories of liability unavailable under each PLA.[12]

V. PLAINTIFFS' FRAUD CLAIM MUST BE DISMISSED UNDER THE LAWS OF THIRTEEN STATES FOR FAILURE TO PLEAD A SPECIAL RELATIONSHIP.

This Court previously dismissed Plaintiffs' common law fraud claim (**Count XIII**) under Rule 9(b) without addressing whether Plaintiffs pled the confidential or fiduciary relationship required to state a fraud-by-omission claim under 13 states' laws. Plaintiffs still fail to plead such a relationship, which is a predicate to pleading a duty to disclose in these states.[13] Thus, Plaintiffs'

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indistinguishable" and sought "virtually the same damages."); *Nelson v. C.R. Bard, Inc.*, 553 F. Supp. 3d 343, 349-50 (S.D. Miss. 2021) (Mississippi PLA subsumed CPA claim that "involve[d] the recovery of damages related to an allegedly defective product"); *Elward v. Electrolux Home Prods., Inc.*, 264 F. Supp. 3d 877, 892 (N.D. Ill. 2017) ("[C]laims based solely on physical harm caused by a product must be brought under the IPLA.") (citation omitted).

[10] *See Roeder v. Am. Med. Sys., Inc.*, No. 20-1051-JWB, 2021 WL 4819442, at *3 (D. Kan. Oct. 15, 2021) (Kansas PLA limited to negligence, breach of warranty, and strict liability); *Price v. Luster Prods. Inc.*, No. CV 21-1036, 2022 WL 1719274, at *7 (E.D. La. May 27, 2022) (Louisiana PLA limited to unreasonably dangerous construction, design, lack of adequate warning, and nonconformity with express warranty); *Gremo v. Bayer Corp.*, 469 F. Supp. 3d 240, 251 (D.N.J. 2020) (New Jersey PLA limited to design defect, manufacturing defect, or warnings defect); *Einbecker v. Gates Corp.*, No. 1-22-62, 2024 WL 416332, at *4 (Ct. App. Ohio Feb. 5, 2024) (Ohio PLA limited to defects in manufacture, construction, design, or formulation; defects due to inadequate warning; and nonconformance with a representation by the manufacturer).

[11] For example, under their New Jersey PLA claim, Plaintiffs assert theories of liability for, *inter alia*, strict liability design defect, negligent design, and medical monitoring. PISAC ¶¶ 1802-03.

[12] If this Court determines that any of Plaintiffs' common law claims must be dismissed, Plaintiffs' corresponding allegations of liability should be dismissed as to (or struck from) all PLA claims (**Counts XXIII *through* XXXI**).

[13] Certain states may also imply a duty to disclose if the defendant made an affirmative statement about a relevant safety feature of a product that was made misleading by the purported omission.

fraudulent omission claims under these states' laws fail to state a claim under Rule 12(b)(6).[14]

VI. PLAINTIFFS' CONSUMER PROTECTION CLAIMS FAIL ON MULTIPLE STATUTE-SPECIFIC GROUNDS.

A. North Dakota's Deceptive Trade Practices Act Has No Private Right of Action.

Plaintiffs' North Dakota Deceptive Trade Practices Act claim (**Count XVI(31)**) should be dismissed because there is no private right of action for damages under that statute. *See DJ Coleman, Inc. v. Nufarm Americas, Inc.*, 693 F. Supp. 2d 1055, 1075 (D.N.D. 2010) ("By creating a private right of action for injunctive relief, but not for damages, the North Dakota [legislature] . . . has clearly expressed its intent to not create a private remedy for damages.").

B. Utah's Consumer Sales Practices Act Excludes Personal Injury Claims.

Plaintiffs' Utah Consumer Sales Practices Act claim (**Count XVI(37)**) fails because that statute does not apply to "claim[s] for personal injury" like those Plaintiffs assert here. *See In re Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 14 C 1748, 2017 WL 1836443, at *10 (N.D. Ill. May 8, 2017); *see also Jackson v. Philip Morris Inc.*, 46 F. Supp. 2d 1217, 1220-21 (D.

See, e.g., *Costa v. FCA US LLC*, 542 F. Supp. 3d 83, 100-01 (D. Mass. 2021). Plaintiffs cannot rely on this exception because they have disavowed any misrepresentation-based fraud theory. *See* January 24, 2024 Opinion (ECF No. 2471) at 3 (noting Plaintiffs sought leave to amend to "clarify that their common law fraud claim (count XIII) is based on the theory of fraudulent omission, not commission"). In any event, this exception does not apply because Plaintiffs have not pled any representation by Respironics regarding the safety of the foam, much less reliance.

[14] *See White v. Volkswagen Grp. of Am., Inc.*, No. 2:11-CV-02243, 2013 WL 685298, at *9 (W.D. Ark. Feb. 25, 2013); *R.J. Reynolds Tobacco Co. v. Whitmire*, 260 So. 3d 536, 538-39 (Fla. Dist. Ct. App. 2018); *McCabe v. Daimler AG*, 160 F. Supp. 3d 1337, 1352 (N.D. Ga. 2015); *Flynn v. FCA US LLC*, 327 F.R.D. 206, 218 (S.D. Ill. 2018); *Estate of White ex rel. White v. R.J. Reynolds Tobacco Co.*, 109 F. Supp. 2d 424, 431 (D. Md. 2000); *Costa v. FCA US LLC*, 542 F. Supp. 3d 83, 100-01 (D. Mass. 2021); *Ruth v. A.O. Smith Corp.*, 4-CV-18912, 2005 WL 2978694, at *4 (N.D. Ohio Oct. 11, 2005) (applying Mississippi law); *Las Vegas Metro. Police Dep't v. Harris Corp., M/A Com, Inc.*, No. 13-cv-01780, 2015 WL 895054, at *7 (D. Nev. Mar. 3, 2015); *Matanky v. Gen. Motors LLC*, 370 F. Supp. 3d 772, 795 (E.D. Mich. 2019) (applying Ohio law); *Martell v. Gen. Motors LLC*, 492 F. Supp. 3d 1131, 1143 (D. Or. 2020); *Gaines v. Krawczyk*, 354 F. Supp. 2d 573, 586 (W.D. Pa. 2004) (Cercone, J.); *Taggart v. Ford Motor Credit Co.*, 462 N.W.2d 493, 499 (S.D. 1990); *McCabe*, 160 F. Supp. 3d at 1358 (applying Virginia law).

Utah 1998) (a personal injury claim is "excluded from available actions under the [UCSPA]").

C. Sixteen Consumer Protection Statutes Apply Only to "Consumer Goods," Not to Prescription Medical Devices.

Sixteen jurisdictions limit their consumer protection statutes to claims involving consumer goods, defined as goods that a consumer might purchase (or, in some jurisdictions, lease) for "personal, family, or household" use.[15] These statutes' plain language, informed by their purpose, historical context, as well as relevant caselaw, confirm that medical devices prescribed by a doctor are ***not*** consumer goods within the purview of these statutes. Given their restricted prescription-based distribution, FDA-regulation, and the absence of a direct seller-consumer relationship (it is the physician who decides what therapy is appropriate and what device to prescribe), a statutory consumer protection claim cannot be stated in any of these jurisdictions.[16]

Plaintiffs allege they "are consumers who purchased, leased, or used Recalled Devices ***for personal and/or household purposes***." *E.g.*, PISAC ¶¶ 883, 908 (emphasis added).[17] The R&R assumed the devices were "consumer goods" under the laws of any state that lacks caselaw expressly holding that prescription medical devices are not "personal, household, or family" goods. *See* R&R at 93-105. As this Court set out in its recent opinion on Respironics' motion to dismiss Plaintiffs' medical monitoring claims, that assumption is inconsistent with Third Circuit precedent

[15] *E.g.*, Ala. Code § 8-19-3(4) (applying only to "good or services for personal, family, or household use"); Cal. Civ. Code § 1761(a) (applying only to "chattels bought or leased for use primarily for personal, family, or household purposes"); D.C. Code § 28-3901(a)(2) (applying only to goods "normally use[d] for personal, household, or family purpose[s]"); *see also* 815 Ill. Comp. Stats. 505/1(e); Ind. Code § 24-5-0.5-2(a)(1)-(2); Ky. Rev. Stat. § 367.220(1), Md. Code Ann., Com. Law, § 13-101(c)(2)(iii); Mich. Comp. Laws § 445.902(g), Miss. Code § 75-24-15(1), Mo. Stat. § 407.025(1); Mont. Code § 30-14-102(1); R.I. Gen. Laws § 6-13.1-5.2(a), Vt. Stat. tit. 9, § 2451a(1), Va. Code § 59.1-198, W. Va. Code § 46A-6-102(2); Wyo. Stat. § 40-12-102(a)(ii).
[16] **Counts XVI(1), (4), (9), (13), (14), (16), (17), (19), (22)-(24), (34), (39), (40), (41), and (43)**.
[17] *See also* Section VI.H, *infra* (regarding lack of standing for users and lessees of devices).

clarifying federal courts' "[d]uty to interpret, not expand, state law."[18] Plaintiffs' claims would require this Court to impermissibly expand state law by permitting claims under statutes that do not expressly refer to prescription medical devices and have not been interpreted by state courts to permit claims concerning physician-prescribed medical devices.[19]

Caselaw from six of the 16 jurisdictions—all of which utilize a substantively similar statutory definition—makes plain that prescription medical devices are not consumer goods for personal or household use. For example, in *Otis-Wisher v. Medtronic, Inc*., the Second Circuit affirmed dismissal of a Vermont consumer protection claim based on a prescription device. 616 Fed. App'x 433, 435 (2d Cir. June 9, 2015). The act "defines a 'consumer' as a 'person who purchases, leases, contracts for, or otherwise agrees to pay consideration for goods or services . . . for his or her use or benefit or the use or benefit of a member of his or her household." *Id.* (quoting Vt. Stat. tit. 9, § 2451a(1)). Plaintiff was not a "consumer" because the device at issue was "not available for consumer purchase," but rather "was prescribed" by a doctor. *Id.*

Interpreting similar language in the consumer-focused Magnuson-Moss Warranty Act, *Kanter v. Warner-Lambert Co*. held that FDA-regulated products were not "consumer product[s]," which the statute defined as "any tangible personal property which is distributed in commerce and which is normally used for personal, family, or household purposes." 122 Cal. Rptr. 2d 72, 86 (Cal. App. 2002) (alternation in original). Neither prescription drugs nor medical devices were considered "consumer products" because "the FDCA and its implementing regulations govern the

[18] Memorandum Opinion [re: Respironics' motion to dismiss the second amended class action complaint for medical monitoring] (Feb. 14, 2024) (Conti, J.), ECF No. 2521, at *7-8 ("MM Op.").
[19] The 16 statutes at issue, adopted in the '60s and '70s, were not intended to regulate the marketing of prescription devices otherwise regulated under the FDCA. Rather, they were intended to regulate "relatively common cash and credit transactions in which [consumers] engage on a regular basis." *State ex rel. McGraw v. Bear, Stearns & Co.*, 618 S.E.2d 582, 587 (W. Va. 2005).

labeling at issue here." *Id.*; *cf. Forcellati v. Hyland's, Inc.*, 876 F. Supp. 2d 1155, 1165-66 (C.D. Cal. 2012) (holding homeopathic products, ***as opposed to prescription products***, are "consumer products"); *see also De Bouse v. Bayer*, 922 N.E.2d 309, 318 (Ill. 2009) (finding the "sale" of prescription medication beyond the scope of that state's consumer protection statute). Courts from the relevant jurisdictions construing statutes that have a similar purpose of protecting consumers in "consumer goods" transactions have similarly concluded that prescription medical products are not consumer goods for "personal, family, or household use."[20] Other courts interpreting identical statutory language have reached the same conclusion.[21]

Likewise, courts interpreting similar consumer protection language have concluded that medical devices prescribed for use at home (like those at issue here) are not "consumer goods." For example, courts have found that insulin pumps, prescription medical devices which patients take with them and use at home, ***do not*** fit within the definition of "personal, family, or household" goods. *See Lightner v. Medtronic Inc.*, No. CV2010942, 2021 WL 4731351, at *7 (C.D. Cal. May 10, 2021) (California consumer-warranty statute, which applies to "consumer goods . . . used,

[20] *See Kemp v. Pfizer, Inc.*, 835 F. Supp. 1015, 1024-25 (E.D. Mich. 1993) ("[M]edical 'devices' covered by the Federal Food, Drug, and Cosmetic Act are specifically not included in the CPSA's definition of consumer products."); *Collins v. Davol, Inc.*, 56 F. Supp. 3d 1222, 1232 n.9 (N.D. Ala. 2014) ("a [medical] device is clearly inconsistent with the Alabama Uniform Commercial Code's definition of 'consumer good,' i.e. 'goods that are used or bought for use primarily for personal, family, or household purposes'") (citation omitted); *McCurdy v. Wright Med. Tech., Inc.*, No. CV 19-1898-CFC, 2020 WL 906329, at *6-7 (D. Del. Feb. 25, 2020), *report and recommendation adopted in relevant part*, 2020 WL 3118647 (D. Del. June 12, 2020) (under Alabama UCC statute, "a medical device is a non-consumer good"); *Hogan v. Md. State Dental Ass'n*, 843 A.2d 902, 906 (Md. Spec. App. 2004) (dental fillings were not goods "primarily for personal, household, family, or agricultural purposes"); *Pease v. Abbott Labs., Inc.*, No. JKB-12-1844, 2013 WL 174478, at *2 (D. Md. 2013) ("prescription drugs are not 'consumer goods'"); *Kemp*, 835 F. Supp. at 1024-25 ("medical devices are not . . . consumer products").

[21] For example, courts interpreting the Ohio consumer protection statute with the same language exclude prescription medical devices. *See Reeves v. PharmaJet, Inc.*, 846 F. Supp. 2d 791, 799 n.2 (N.D. Ohio 2012) ("[A] prescription medical device is not a good for personal, family or household use and thus is not a consumer good as defined by the OCSPA.").

bought, or leased primarily for personal, family, or household purposes," found not to apply "because the insulin Pump is a prescription medical device not sold at retail").[22]

In short, precedent establishes that a prescription medical device is not a consumer good for personal or household use giving rise to a consumer protection claim. Any contrary interpretation would amount to an impermissible expansion of state law. MM Op. at 14-15. The statutory language does not permit extension to cover prescription medical devices.[23]

D. Omissions Cannot Support Wisconsin Deceptive Trade Practices Act Claims.

Plaintiffs' Wisconsin Deceptive Trade Practices Act claim (**Count XVI(42)**) fails because it is premised solely on omissions, but "only affirmative assertions, representations, or statements of fact that are false, deceptive, or misleading" are actionable under the statute.[24] *See Tietsworth v. Harley-Davidson, Inc.*, 677 N.W.2d 233, 245 (Wis. 2004).

E. Five Consumer Protection Claims Fail For Lack of Pre-Suit Notice.

Five of Plaintiffs' consumer protection claims[25] require timely and compliant ***pre-suit*** notice as a condition precedent to asserting a claim.[26] Plaintiffs muster only conclusory allegations

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[22] *See also In re Minnesota Breast Implant Litig.*, 36 F. Supp. 2d 863, 876 (D. Minn. 1998) ("Plaintiffs' [products] do not constitute 'consumer products' under the [Magnuson-Moss] Act because these implants are not readily accessible to all consumers"); *Goldsmith v. Mentor Corp.*, 913 F. Supp. 56, 63 (D.N.H. 1995) (under the Magnuson-Moss Act, "a medical device regulated under the MDA, is not a consumer product.").

[23] As Plaintiffs and the Special Master have recognized, some courts have reached a different conclusion in the context of prescription medication. Those decisions are at odds with the rationale articulated by the courts that have closely analyzed the definition and scope of "consumer goods" in the state statutes. *E.g.*, R&R at 95 (*In re Vioxx Class Cases*), 96 (*In re Actiq Sales & Mktg. Practices Litig.*), 97-98 (*Mayor & City Council of Baltimore v. GlaxoSmithKline, LLC*); *but see White v. Wyeth*, 705 S.E.2d 828, 838 (W. Va. 2010) ("Prescription drug cases are not the type of private causes of action contemplated under the terms and purposes of the [statute] because the consumer can not and does not decide what product to purchase.").

[24] *See* PISAC ¶¶ 1640-50. PISAC ¶¶ 1647-48 and 1654-56 refer to misstatements, but without any factual support, and the pleading of this claim makes clear that Plaintiffs allege only omissions.

[25] **Counts XVI (4), (14), (18), (41) and (43)**.

[26] Cal. Civ. Code § 1782(a); Ind. Code §§ 24-5-05.-5, 24-5-0.5-2(a)(5)-(8); Mass. Gen. L. Ch. 93A § 1-9; W. Va. Code Ann. § 46A-5-108(a); Wyo. Stat. Ann. § 40-12-109.

that they "have complied or substantially complied with all applicable notice requirements . . . ." *E.g.*, PISAC ¶¶ 701, 955. Plaintiffs refer only to letters dated September 8, 2021, and May 16, 2022,[27] which purported to provide ***post-suit*** notice of economic damage claims—***the letters do not assert personal injury claims of any sort, making them both untimely and facially deficient***. These five PISAC counts should be dismissed while preserving the ability of compliant individual plaintiffs who can satisfy the required pre-suit notice elements missing in the PISAC to proceed.[28]

F. Plaintiffs Failed to Comply with Prerequisites to Sue Under the Mississippi Consumer Protection Act.

As a condition precedent to filing a Mississippi Consumer Protection Act ("MCPA") claim (**Count XVI(22)**), plaintiffs must make "a reasonable attempt to resolve any claim through an informal dispute settlement program approved by the Attorney General." Miss. Code § 75-24-15(2). Plaintiffs allege having done so, pointing to their purported "notice letters" of September 2021 and May 2022. *See* PISAC ¶ 1155. But as noted above, those are both ***post-suit letters and concern economic loss, not personal injury claims***.[29]

G. Plaintiffs Waived Their Alabama Deceptive Trade Practices Act Claim.

Plaintiffs pursuing civil remedies under the Alabama Deceptive Trade Practices Act ("ADTPA") must "surrender" "all other rights and remedies available at common law, by statute

[27] Copies of the letters and responses are attached as Exhibits A-D to the Motion and may be considered by the Court to evaluate Plaintiffs' claims. *See Beto v. Barkley*, 706 F. App'x 761, 765 (3d Cir. 2017) (court may consider documents incorporated by reference in the complaint).

[28] This Court in its Opinion requested the parties address "what constitutes 'presuit notice' in the context of a master complaint in an MDL." *See* Opinion at 7 n.8. Dismissal of these counts in the PISAC is warranted on a "master" global basis. However, individuals could retain the ability to state a claim under these statutes if plaintiffs, in their respective individual Short Form Complaints, are able to factually attest to their compliance with the conditions precedent to the consumer protection statutes under which they bring a claim. Failure by individual plaintiffs to do so in the Short Form Complaints, too, would result in dismissal of any individual consumer protection claims they might individually seek to pursue.

[29] The same remedial approach proposed in n.28, *supra*, also applies to Plaintiffs bringing Mississippi Consumer Protection Act claims. Miss. Code § 75-24-15(2).

or otherwise, for fraud, misrepresentation, deceit, suppression of material facts or fraudulent concealment arising out of any act, occurrence or transaction actionable under [the ADTPA]." Ala. Code § 8-19-15. Because Plaintiffs assert fraud and other claims arising out of the same alleged conduct as their ADTPA claim, Plaintiffs pursuing an ADTPA claim (**Count XVI(1)**) should "be deemed to have procedurally waived [their] claim under the ADTPA." *See Holmes v. Behr Process Corp.*, No. 2:15-CV-0454, 2015 WL 7252662, at *3 (N.D. Ala. Nov. 17, 2015); *see also Carter v. L'Oreal USA, Inc.*, No. 2:16-CV-508, 2019 WL 4786949, at *9 (S.D. Ala. Sept. 30, 2019) (the ADTPA is "exclusive of other remedies available under Alabama law.").[30]

H. Certain Plaintiffs Lack Statutory Standing to Sue.

Ten consumer protection statutes afford a private right of action only to consumers who "rented or purchased" a product.[31] Two statutes afford a private right of action only to consumers who "purchased" a product.[32] The claims of Plaintiffs who allege only to have "used" a device must be dismissed with prejudice under all twelve statutes (**Counts XVI (1), (4), (11), (12), (16) (22), (23), (24), (34), and (41)**). Under two additional statutes, the claims of Plaintiffs who allege only to have "used" or "leased" a device must also be dismissed (**Counts XVI(7) and (13)**).

CONCLUSION

For all the foregoing reasons, the aforementioned claims in the PISAC should be dismissed in their entirety with prejudice.

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[30] *But see Boddison v. Gen. Motors LLC*, No. 8:20-CV-2139, 2021 WL 2685770, at *3 (M.D. Fla. June 30, 2021). Respironics submits that *Holmes* and *Carter*—***issued by federal courts in Alabama***—are correct in holding that § 8-19-15 is an exclusive remedy even at the pleading stage.
[31] *See* Ala. Code §§ 8-19-10, 8-19-3(4), 8-19-3(12); Cal. Civ. Code §§ 1780(a), (d); Ga. Code §§ 10-1-399(a), 10-1-392(a)(7), 10-1-392(a)(10), 10-1-392(a)(6); Idaho Code § 48-608; Ky. Rev. Stat. § 367.220(1); Miss. Code § 75-24-15(1); Mo. Rev. Stat. § 407.025(1); Mont. Code §§ 30-14-133(1)(a), 30-14-102(1); R.I. Gen. Laws 1956, § 6-13.1-5.2; W. Va. Code, § 46A-6-106(a).
[32] *See* Colo. C.R.S.A. § 6-1-113(1)(a),(b); 6-1-113(1)(b); *Amon on Behalf of Amon v. Harrison*, No. 91 C 980, 1994 WL 532025, at *3 (N.D. Ill. Sept. 29, 1994).

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 11, 2024, the foregoing document was electronically filed with the Clerk of the Court and served upon counsel of record through the Court's ECF system.

/s/ John P. Lavelle, Jr.
John P. Lavelle, Jr.